510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date

July 21, 2010

Manufacturer

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Contact person: Mr. Dave Kim

Trade/Proprietary Name:

XmaruView V1

Common Name:

Radiological Image Processing System

Classification Name:

System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class2)

Description:

XmaruView V1 is a radiographic image capture program in charge of variety of image related works, including photographing Digital Radiography, acquiring and processing the images, and the image management.

XmaruView V1 provides integrated controls the flat-panel detector and the X-ray generator of a radiographic system to perform image acquisitions and image processing. Its own database storage capability enables a user the convenient management of patient images and data. In addition, it supports DICOM output for a seamless integration with the operating environment where PACS is installed.

XmaruView V1 has been developed to meet the requirements of hospitals to provide a seamless work flow in the heavy work load environment and thus is equipped with a number of relevant convenience functions.

Indication for use:

XmaruView V1 software is to make the processing and administration of medical X-ray images as efficient as possible. Functions to be carried out using XmaruView V1 is, for example, but not limited to, adjustment of window leveling, rotation, zoom, and measurements. XmaruView V1 software can control X-ray generator acquisition settings. XmaruView V1 is not approved for the acquisition of mammographic image data and it cannot be used to interpret mammographic image date either. XmaruView V1 is meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data. XmaruView V1 is complying with DICOM standards to assure optimum communications between network systems.

Predicate Device:

Manufacturer	: Oehm und Rehbein GmbH.
Device	: dicomPACS® DX-R 1.6
510(k) Number	: K091364 (Decision Date – DEC 11, 2009)

Substantial Equivalence:

The XmaruView V1 described in this 510(k) has the same intended use and similar technical

characteristics as the dicomPACS® DX-R 1.6 of Oehm und Rehbein GmbH.

The model dicomPACS® DX-R is the primary predicate device. The subject device and predicate device are substantially equivalent, having the same/similar indications for use and functionalities like operation software, resolution, X-ray generator control, image processing, windowing, zoom, rotation, DICOM worklist, DICOM store and DICOM print. The differences are cosmetic, arrangement and components use only. Both subject device and dicomPACS® DX-R are categorized in product code LLZ; equivalence between these models is evident.

Differences between the subject device and predicate device include processor, RAM requirement, networking and image format size. These differences do not raise any new questions of safety or effectiveness.

Safety and Performance Data:

- NEMA PS 3.1-3.18 Digital Imaging and Communications in Medicine (DICOM) set (2008)
- IEC 62304 Medical device software – Software life-cycle processes : 2006
- ISO 14971 Medical Devices – Application of risk management to medical device : 2007

Conclusion:

None of the modifications alter the Indications for Use in a significant way, nor the fundamental scientific technology, and do not introduce a fundamentally new scientific technology. Therefore, it is our opinion that the XmaruView V1 described in this submission is substantially equivalent to the predicate device.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

VATECH Co., Ltd.
% Mr. Dave Kim
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AUG 10 2011

Re: K102078
Trade/Device Name: Radiological Image Processing System/XmaruView V1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 9, 2011
Received: May 17, 2011

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K102078

Device Name: Radiological Image Processing System /XmaruView V1

Indications for Use:

XmaruView V1 software is to make the processing and administration of medical X-ray images as efficient as possible. Functions to be carried out using XmaruView V1 is, for example, but not limited to, adjustment of window leveling, rotation, zoom, and measurements. XmaruView V1 software can control X-ray generator acquisition settings. XmaruView V1 is not approved for the acquisition of mammographic image data and it cannot be used to interpret mammographic image date either. XmaruView V1 is meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data. XmaruView V1 is complying with DICOM standards to assure optimum communications between network systems.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102078